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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,609

10/05/2005

Roland Brugger

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6363

23117

7590

03/18/2009

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EXAMINER

SAYALA, CHHAYA D

ART UNIT

PAPER NUMBER

1794

MAIL DATE

DELIVERY MODE

03/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,609	Applicant(s) BRUGGER ET AL.	
	Examiner C. SAYALA	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/5/2005</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102/Claim Rejections - 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 6-10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Prieels et al. (US Patent 4726948).

The reference teaches that lactoferrin can be provided as capsules or tablets wherein starch is used to bind the pharmaceutical preparation and is used as a food stuff or in animal feeds. See col. 4, lines 25-50. The composition also contains fat (see Example 1). See also col. 1, lines 1-2. These claims are written in a product-by-process format and as such, it is the novelty of the instantly claimed product that need be established and not that of the recited process steps. *In re Brown*, 173 USPQ 685 (CCPA 1972); *In re Wertheim*, 191 USPQ (CCPA 1976). "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ

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964, 966 (Fed. Cir. 1985). With regard to claims 6, 8-10, applicant has chosen to describe his product with physical characteristics that are beyond measurement by this Office and as a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith. See *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972) at 59 CCPA 1041. In any event, whether the solids of Prieels are thermostable or not, which fact cannot be ascertained by the Office, the solids are discrete and are fed in animal feedstuff, and therefore, it is being held that the other limitations have been met by this reference.

Claim Rejections - 35 USC § 103

2. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ford et al. (The Journal of Pediatrics, vol. 90(1), pp. 29-35, 1977) in view of Prieels et al. and Gao et al. (US Patent 5871802) and further in view of WO 98/18610 and Busk (US Patent 4694881).

Ford has been applied only to establish that lactoferrin is heat-sensitive. See the abstract. Similarly, Prieels has been applied to show that combining lactoferrin in animal feeds or in foodstuff as solid particles granulated or tableted with starch was also known in the art at the time of making the invention. See col. 1, lines 15-20, col. 4, lines 25-50. Note that Prieels teaches that lactoferrin has antibacterial properties and therefore it is widely used as a component of foodstuff or in animal feedstuff (abstract).

The WO patent to Van Lengerich teaches the same process as claimed herein for heat sensitive compounds that can be used in pharmaceuticals, as biologically or nutritionally active compounds without destroying its activity or matrix. The process includes mixing the active compound with starch such as wheat durum (page 12), or proteins such as gluten (page 13), and using as a lubricant or a hydrophobic agent, fat or oil, (see pages 13, line 6), and that the active compound can be in a powder form (lines 18-19 @ page 11). It is well known that lactoferrin is available in powder form (see Prieels and the instant specification at pages 1-2). The WO patent teaches using an extruder for mixing and heating the mixture using low shear and temperatures of at least about 100 degrees Celsius. See page 22, line 12+. The temperature is recommended in order to gelatinize the starch matrix. Page 21 describes the active compound being embedded or encapsulated into the matrix. At page 9, the patent teaches that after the low temperature heating and low shearing in the extruder, the admixture is extruded and cut and dried. See lines 8-20. The extrudate is pellets, tablets, etc. Page 28, lines 20-28. The patent teaches that these products can be used in food stuffs and animal feeds. See page 35, lines 7-8. Claim 18 recites the encapsulated active being a heat sensitive pharmaceutical, nutritional or a biologically active component. Claim 20 shows a number of antimicrobials being benefited by this process of the patent.

The WO patent does not specifically teach lactoferrin as the active. However, since Prieels teaches that lactoferrin is an antimicrobial and Ford teaches that it is heat sensitive, then to particulate lactoferrin using the WO patent would have been prima

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facie obvious based on the fact that the WO patent is drawn to a number of antimicrobials being benefited by this method of embedding the active in starch or protein using low temperature and low shear.

While the WO patent does not show the temperature as low as 60 degrees or below, Gao teaches cold pelleting using 140 degrees F for milk proteins is beneficial. See col. 2, lines 7-20 and Example 1. Also see col. 3, lines 33-45. The extruder temperatures shown are the same and are specifically drawn for milk proteins. Therefore, while it was known that lactoferrin is a milk protein and that it is heat sensitive, Gao's patent clearly establishes that prior art having been aware of these facts also had already established the low temperatures to be used for pelleting milk proteins at temperatures of 140⁰ F or less. To incorporate this in the WO patent would have been prima facie obvious, particularly since Gao specifically calls for such a temperature with regard to milk proteins.

While the WO patent does not teach a horizontal screw extruder, and while it was already known that extruders are either vertical or horizontal screw extruders, Busk has been applied here only to show that the choice of a horizontal screw extruder would have been obvious based on the fact that it was known in the art that liquids do not work for horizontal screw extruders and therefore the use of a powder or a solid feed would render this choice obvious. See col. 6, lines 18-22. Also, note the figures in the WO patent that show the type of extruders being claimed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Sayala, whose telephone number is (571) 272-1405. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/C. SAYALA/
Primary Examiner, Art Unit 1794**

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